

**REMARKS**

Claim 7 is amended to improve English syntax in accordance with the Examiner's suggestion; claims 8-10 and 12 are canceled to advance prosecution; claims 17 and 20 are amended to correct an error in wording (The original French specification refers to "an effect of IL-17 on the production of IL-4; thus IL-17 affects IL-4.). No issue of new matter arises.

***Claim Objections***

Claims 7-9 were objected to as allegedly being substantial duplicates of claim 10. Applicants respectfully traverse this objection.

In the enablement rejection the Examiner acknowledges that methods of treating IDDM are different from all possible autoimmune disease. See, e.g., the June 13 Office Action at page 4, last paragraph. Thus a difference in scope is apparent based on the difference in claim wording. Nevertheless claims 8 and 9 are canceled to advance prosecution at this stage with the possibility of claiming similar subject matter remaining possible in subsequent application prosecution. Reconsideration and withdrawal of this objection are respectfully requested.

***Rejection under 35 U.S.C. §112, first paragraph - enablement***

Claims 2-4, 6-15 and 17-21 were rejected under 35 U.S.C. §112 as allegedly lacking enablement. Claims 8, 9 and 12 are canceled. The Office Action acknowledged that the specification was enabling for treating diabetes mellitus, pharmaceutical compositions, or a process for producing pharmaceutical compositions comprising T-cells incubated with IL-7, wherein the T-cells are thymocytes. The rejection however, is not properly based on US patent law. "Undue experimentation" is the standard to be applied when considering enablement. The Office Action at page 5, first paragraph, last sentence mentions undue experimentation, but improperly applies the standard. The standard is not whether practicing the invention for treatment of "all possible autoimmune disorders" would require undue experimentation, but whether undue experimentation would be required to practice the claimed invention. Inoperative embodiments are permitted. See e.g., Smythe

As we have said before, it is almost always possible to so construe a claim as to have it read on ~~inoperative~~ embodiments. In re Cook, 439 F.2d 730, 734, 58 CCPA 1049, 1054 (1971), but the alternative of requiring an applicant to be so specific in his claims "as to exclude materials known to be ~~inoperative~~ and [which] even those *not* skilled in the art would not try" would result in claims which would fail to comply with 35 U.S.C. § 112, second paragraph, because they would be so detailed as to obscure, rather than to particularly point out and distinctly claim, the invention. In re Myers, 410 F.2d 420, 56 CCPA 1129 (1969), quoted with approval in In re Anderson, 471 F.2d 1237 (CCPA 1973). [Emphasis added.]

480 F.2d 1376.

See also The MPEP:

#### 2164.08(b) Inoperative Subject Matter

The presence of inoperative embodiments within the scope of a claim does not necessarily render a claim nonenabled. The standard is whether a skilled person could determine which embodiments that were conceived, but not yet made, would be inoperative or operative with expenditure of no more effort than is normally required in the art. Atlas Powder Co. v. E.I. du Pont de Nemours & Co., 750 F.2d 1569, 1577, 224 USPQ 409, 414 (Fed. Cir. 1984) (prophetic examples do not make the disclosure nonenabling).

Although, typically, inoperative embodiments are excluded by language in a claim (e.g., preamble), the scope of the claim may still not be enabled where undue experimentation is involved in determining those embodiments that are operable. A disclosure of a large number of operable embodiments and the identification of a single inoperative embodiment did not render a claim broader than the enabled scope because undue experimentation was not involved in determining those embodiments that were operable. In re Angstadt, 537 F.2d 498, 502-503, 190 USPQ 214, 218 (CCPA 1976). However, claims reading on significant numbers of inoperative embodiments would render claims nonenabled when the specification does not clearly identify the operative embodiments and undue experimentation is involved in determining those that are operative. Atlas Powder Co. v. E.I. duPont de Nemours & Co., 750 F.2d 1569, 1577, 224 USPQ 409, 414 (Fed. Cir. 1984); In re Cook, 439 F.2d 730, 735, 169 USPQ 298, 302 (CCPA 1971).

The presence of one or even many inoperative embodiments does not alone support an enablement rejection. See e.g., Wands, 8 USPQ2d 1400. In Wands, millions of molecules were featured, but only a very small fraction met the claim limitations. The variability of amino acid sequence was great and not predictable before the

compounds were tested. The specific sequences were not even predictable after results indicating which specific compounds met the claim limitations were determined. Simply measuring binding characteristics (to screen for operative embodiments) does not provide sequence information. (Also in Wands, many of the molecules produced were never tested for binding.) No presumption was made that failure to test the millions of compounds produced was evidence supporting a requirement for undue experimentation. Rather the Wands guidance clearly teaches that undue experimentation relates to practicing an additional or the next embodiment, clearly not a requirement that all must be tested. Accordingly, Wands makes it quite clear that breadth of scope and the possibility or even certainty of inoperative embodiments cannot constitute a proper basis for rejection. Sheer number of embodiments, e.g., compounds as in Wands (or the smaller number of autoimmune disease related to a failure of immunoregulation by CD4+ cells or diminished production of IL-4 (present claim 17)), that potentially meet the claim limitations is not a proper basis for rejection. The proper basis for an enablement rejection is necessity for undue experimentation. Inoperative embodiments alone do not create a presumption of undue experimentation. Accordingly insofar as the rejection relies on assertions of, "any" "many" "all" "genus" etc., for support, the rejection is improper. Nowhere in the Office Action is the scope of the experimentation that is considered to be "undue" characterized for a single embodiment! The reliance on the "undue" nature appears to rest on reading into the claims an unrecited limitation, i.e., to require testing all possible embodiments in order to practice the claimed invention ("practicing the claimed method of treatment of all possible autoimmune disorders") (emphasis added). One skilled in the art would rely on the skill in the art for background and on the instant disclosure as a guide to select potential autoimmune disease related to a failure of immunoregulation by CD4+ cells or diminished production of IL-4 that the skilled artisan would find of interest. Testing of the claimed treatment method for any one embodiment or even several embodiments would not rise to a level of undue experimentation. Accordingly Applicants respectfully request reconsideration and withdrawal of this rejection.

*Rejections under 35 U.S.C. §112, second paragraph*

Claims 2-4, 6-15 and 17-21 were alleged to be indefinite with respect to the expression, “effecting IL-4 production”. Applicants express their appreciation to the Examiner for calling attention to this inelegant choice of words. The proper term is “affecting”. See discussion in the first paragraph of remarks. No issue of new matter arises. Claim 17 and 20 are amended to obviate this rejection. Reconsideration and withdrawal of this rejection are respectfully requested.

Claims 2-4, 6-15 and 17-21 were alleged to be indefinite with respect to the expression, related to failure of immunoregulation of CD4<sup>+</sup> cells. Applicants respectfully traverse this rejection. While the Office Action proposes the expression to encompass virtually any biological activity attributed to a CD4<sup>+</sup> cell, this proposal is improper. The scope is limited to “failure of immunoregulation”. Applicants respectfully submit that even the broader scope would not raise an indefiniteness issue. The reading of a claim during prosecution in the USPTO is “the broadest reasonable scope”. Thus no issue of indefiniteness arises by an Examiner’s reading that a claim reasonably encompasses a broad scope. Reconsideration and withdrawal of this rejection are respectfully requested.

*Rejections under 35 U.S.C. §102*

1. Claims 2-4, 15 and 17 were rejected under 35 U.S.C. §102(e) over Grabstein. The Office Action commented that the expression “effecting IL-4 production” was unclear. As discussed above, the claims have been properly amended. The Office Action acknowledges that Grabstein nowhere specifically recites IL-4 production. Accordingly Grabstein cannot properly be said to teach all claim limitations. Accordingly, an anticipation rejection is clearly improper. Reconsideration and withdrawal of this rejection are respectfully requested.

2. Claims 2-4, 15 and 17 were rejected under 35 U.S.C. §102(e) over Williams. The Office Action commented that the expression “effecting IL-4 production” was unclear. As discussed above, the claims have been properly amended. The Office Action acknowledges that Williams nowhere specifically recites IL-4 production. Accordingly, Williams cannot properly be said to teach all claim limitations. Accordingly, an anticipation rejection is clearly improper. Reconsideration and withdrawal of this rejection are respectfully requested.

***Rejection under 35 U.S.C. §103***

Claims 2, 3, 6-15 and 17-21 were rejected under 35 U.S.C. §103 over Gombert in view of Jicha. Applicants respectfully traverse this rejection.

In the previous response Applicants argued:

The Gombert reference is not properly cited as prior art against the present application. Applicants attach a copy of the International Search Report indicating that Gombert is published after the claimed priority date. See page 3, the “P,X” notation for the third reference. Because of this, this reference is not properly cited in a prior art rejection, for example under 35 U.S.C. §102(b).

The present Office Action counters: “Thus the inventive entity of the instant application is distinct from the authors of the Gombert reference, and therefore the Gombert reference is indeed evidence of invention by another.” Applicants respectfully submit that authorship is not evidence of inventorship. Accordingly, the Declaration by the inventors in the file of this application should be considered controlling. Bach, Gombert, Herbelin and Morre have submitted a signed Declaration stating they are the inventors. Accordingly, the Gombert reference, should not be considered as evidence of invention by another.

Moreover the Gombert reference appears to have been published after the Claimed date for benefit of priority, February 28, 1996. The Office Action asserts a date of 2/1/1996 as an electronic publication date, but presents no evidence. In the absence of evidence, Applicants respectfully submit that Gombert is not properly considered as prior art. Reconsideration and withdrawal of this rejection are respectfully requested.

If such evidence exists, Applicants respectfully request that it be provided.

***Obviousness-type double patenting rejection***

Applicants acknowledge the obviousness-type double patenting rejections. However, since the present application has no indicated allowable subject matter, it would be premature to require a terminal disclaimer when other actions, for example an amendment to the claims that would invoke 35 U.S.C. §121, might obviate the requirement. Applicants will consider amendment or filing a terminal disclaimer when allowable subject matter is indicated.

***Conclusion***

In view of the above amendments and remarks, Applicants respectfully request reconsideration and withdrawal of all pending objections and rejections. Applicants respectfully submit that the application is now in condition for allowance and request prompt issuance of a Notice of Allowance. Should the Examiner believe that anything further is desirable that might put the application in even better condition for allowance, the Examiner is requested to contact the undersigned at the telephone number listed below.

***Fees***

No fees not otherwise provided for are believed to be necessitated by the instant response. However, should this be in error, authorization is hereby given to charge Deposit Account No. 18-1982 for any underpayment, or to credit any overpayments.

Respectfully submitted,



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